EXHIBIT J

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Judge Honorable Joel Schneider, Magistrate Judge

PLAINTIFFS' SECOND AMENDED SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO DISTRIBUTOR AND WHOLESALER DEFENDANTS

TO ALL DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, and in accordance with the Court's rulings at oral argument on December 11, 2019 and December 18, 2019, and in the Order filed on December 13, 2019, as well as the Court's Order on macro discovery issues filed on November 25, 2019, Plaintiffs propound the following second amended set of requests upon each Distributor/Wholesaler Defendant.[1]

[1] Each request is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303); the parties' representations as reflected in the record of the December 11, 2019 discovery hearing; and the Court's oral rulings at the December 11, 2019 discovery hearing.

DEFINITIONS:

"Active Pharmaceutical Ingredient" ("API") is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

"**API Manufacturer**" is defined as any entity that manufactures the active pharmaceutical ingredient (API) for valsartan.

"**Finished Dose Manufacturer**" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

"Manufacturer Defendants" includes API Manufacturers and Finished Dose Manufacturers including any subsidiaries or affiliated entities.

"**Communication(s)**" means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

"**Documents**" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data

formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all zrequests is January 1, 2012 through the present.

"Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

"Retail Pharmacy Defendants" refers to any and all entities listed as "Retail Pharmacy Defendants" in Plaintiffs' June 17, 2019 Master Complaint (Dkt. No. 121), whether by name or as John Doe defendants, including ANY person or entity acting on any of their behalf including any agents, employees, predecessor entities, or other representatives.

"**TPP**" refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plants, third party payers, and any other health benefit provider in the United States of America and its territories.

"**Valsartan**" or "**VCDs**" means any drug with valsartan as an active ingredient, including the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan-containing drug.

"Recalled Valsartan" or "Recalled VCDs" means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug, that was subject to a voluntary or mandatory recall. This term also includes all valsartan or VCDs that were sold, imported, distributed, dispensed and/or returned or destroyed upon product expiration containing the same NDC code (or a successor NDC code if discontinued) as valsartan or VCDs that were later subject to recall.

"**You**," "**your**" or "**defendant**" shall be used interchangeably and refers to the parties to which these requests are directed.

"Drug Supply Security Chain Act" refers to Pub. L. 113-54 and regulations promulgated thereunder.

"Retail Pharmacy Defendants" refers to any and all entities listed as "Retail Pharmacy Defendants" in Plaintiffs' June 17, 2019 Master Complaint (Dkt. No. 121), including ANY person or entity acting on any of their behalf including any agents, employees, predecessor entities, or other representatives.

"Wholesaler Defendants" refers to and ALL entities listed as "'John Doe' Wholesaler Defendants" in Plaintiffs' June 17, 2019 Master Complaint (Dkt. No. 121), including ANY person or entity acting on any of their behalf including any agents, employees, predecessor entities, or other representatives.

Non-privileged information: These Requests seek only information that is not privileged. This does not relieve any responding Defendant from serving a privilege log consistent with the Federal Rules of Civil Procedure.

DOCUMENTS TO BE PRODUCED

I. SOURCING (UPSTREAM)

1. Documents sufficient to identify when and from whom you purchased VCDs.
2. Documents sufficient to identify the VCDs purchased by you, including quantity/units, NDC codes, batch, lot number, expiration date, and any other unique identifiers.
3. Documents sufficient to identify your receipt of any manufacturer-included packaging or labeling information for VCDs purchased by you (e.g., invoices, bills of lading, packing slips, etc.).
4. The gross and net price paid by you for VCDs identified in Request No. 2.

II. SALES (DOWNSTREAM)

5. Documents sufficient to identify when and to whom you sold VCDs.
6. Documents sufficient to identify the valsartan sold by you, including quantity/units, NDC, batch, lot number, expiration date, and any other unique identifiers (including EDI 867 Product Transfer and Resale Report data).
7. Documents sufficient to identify your distribution of any manufacturer-included packaging or labeling information for VCDs sold by you (e.g., invoices, bills of lading, packing slips, etc.).
8. The gross and net price paid for VCDs sold by you identified in Request No. 6, along with other identifying information about each sale maintained by you in the ordinary course of business.

III. WARRANTIES/STATEMENTS (UPSTREAM)

9. Your policies, procedures, or practices for the types of documents or other information to be provided by a prospective supplier of VCDs purchased by you.
10. Documents sufficient to show the information provided to you by suppliers of VCDs actually purchased by you.
11. Documents relating to, consisting of, or evidencing any research or investigation you conducted on actual or prospective suppliers of VCDs.
12. Documents consisting of or evidencing any warranty or statement made to you by a supplier of VCDs regarding the quality, purity, or bioequivalence of VCDs, including but not limited to any warranties or statements that VCDs were manufactured in compliance with U.S. laws and regulations.

IV. WARRANTIES/STATEMENTS (DOWNSTREAM)

13. Your policies, procedures, or practices for the types of documents or other information and materials to be provided by you (whether such materials were created by you or not) when you sell or distribute VCDs.

14. Documents sufficient to show the information provided by you when you have actually sold or distributed VCDs.
15. Documents consisting of or evidencing any warranty or statement made by you to a purchaser of VCDs regarding the quality, purity, or bioequivalence of VCDs, including but not limited to any warranties or statements that VCDs were manufactured in compliance with U.S. laws and regulations.

V. TESTING/INSPECTION

16. Testing and testing results of VCDs made available to you for VCDs you purchased.
17. Testing (if any) you performed for VCDs, and results thereof.
18. Testing and testing results of VCDs made available by you when you sell VCDs.

VI. DISTRIBUTION CENTERS

19. Documents sufficient to identify your distribution centers from which VCDs were shipped, including location and state(s) of locations served by each distribution center.
20. Documents sufficient to identify your distribution centers that would have received or shipped VCDs subject to recall.

VII. RECALL

21. Your policies, procedures, and practices that govern execution of pharmaceutical recalls.
22. Your policies, procedures, and practices specifically governing the VCD recalls, if any.
23. VCD recall communications you received from anyone.
24. VCD recall communications you made available to anyone.
25. Documents sufficient to identify (by NDC code and lot and batch information and any other unique identifiers) Recalled VCDs: (a) currently on hand; (b) returned by you; or (c) destroyed by you.
26. Documents sufficient to show a list of your employees involved in the recall of VCDs.
27. Documents sufficient to show a list of your warehouse and/or distribution facilities involved in any VCD recalls.

VIII. COMPLIANCE WITH THE DRUG SUPPLY CHAIN SECURITY ACT

28. Documents sufficient to show your obligations under the Drug Supply Chain Security Act and regulations promulgated thereunder, with respect to VCDs.
29. Documents identifying lot-level product tracing or verification, or other product-tracing or verification information, transaction information, history and statements, regarding VCDs.
30. Documents sufficient to show your policies, practices, or procedures for ensuring compliance with the Drug Supply Chain Security Act and regulations promulgated thereunder, with respect to VCDs.
31. Prior to full implementation of the Drug Supply Chain Security Act and regulations promulgated thereunder, all documents identifying lot-level tracing or verification, or other product-tracing or verification information, transaction information, history and

statements, regarding VCDs, including but not limited to, any pedigree documents received for any VCDs.

32. Any FDA Establishment Inspection Reports ("EIRs"), form 483s, correspondence and warning letters regarding your compliance with the Drug Supply Chain Security Act and/or regulations promulgated thereunder, specifically as it relates to data integrity, tracing information, or your processes and procedures for identifying and quarantining suspicious, adulterated or illegitimate product.

IX. LITIGATION AND DOCUMENT PRESERVATION

33. Produce all document retention or destruction policies.
34. Produce all litigation holds you have issued that are related in any way to the above-captioned litigation or to the VCD recalls.

X. COMPLAINTS

35. Documents sufficient to show all complaints you received from anyone concerning the quality, purity, bioequivalence, or contamination of VCDs.

XI. INDEMNITY AGREEMENTS

36. Produce all agreements that you have with anyone that affect your legal obligations or liabilities with regard VCDs including but not limited to indemnity agreements and joint defense agreements.

Dated: January , 2020

/s/ Adam Slater
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CERTIFICATE OF SERVICE

I certify that on the day of December, 2019, I electronically transmitted the attached document to counsel of record for all Retail Pharmacy and Wholesaler Defendants.

/s/ Adam M. Slater